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Subject: FW: GE News & Science

FYI

From: Cournoyer, Patrick <Patrick.Cournoyer@fda.hhs.gov>

Sent: Friday, December 17, 2021 6:23 PM

Subject: GE News & Science

### **NEWS**

### The New Yorker features efforts to improve photosynthesis through biotechnology

- The in-depth reporting describes the work of the RIPE project, which achieved a breakthrough when it boosted plant biomass by 20% by downregulating nonphotochemical quenching
- The reporting goes on to describe other efforts to improve photosynthesis, and it chronicles the successes and pitfalls of the Green Revolution

• The piece closes with perspectives on the need to improve various aspects of society, not just plant science, to successfully feed the future

The New Yorker: Creating a Better Leaf

### U.S. Supreme Court considering Bayer's petition that it review glyphosate cancer cases

- Bayer is facing thousands of lawsuits from patients claiming their cancer was caused by Roundup
- Bayer petitioned the Supreme Court in August to dismiss these claims
- The Supreme Court asked the Administration on Monday for its views on whether the Court should hear the
  case, and the U.S. Solicitor General is expected to file a brief in the coming months with the Administration's
  views
- The EPA has deemed glyphosate to be non-carcinogenic, and Bayer claims EPA would not allow a cancer warning to be printed on the product label

Reuters: Supreme Court asks U.S. government for views on Bayer weedkiller case

## Bayer facing class action lawsuit in Germany from investors who claim the company misled them about the risk of taking over Monsanto

- The plaintiffs are seeking over 1 billion euros
- Bayer bought Monsanto in 2016, just as cancer lawsuits began to explode in the US

Reuters: Bayer faces class action suit over Monsanto takeover in Germany, law firm says

### Group of tree biotechnology proponents petition the Forest Stewardship Council to allow GE trees

- The Forest Stewardship Council currently prohibits the use of GE trees in the forests and products it certifies
- The Council is reviewing its policies and accepted public comment until December 3<sup>rd</sup>

Cornell Alliance for Science: Scientists seize 'once in a decade' opportunity to advocate for genetically engineered trees

### COMMENTARY

### FDA responds to July 2021 commentary pointing to regulatory and IP barriers to progress with xenotransplantation

- Peter Marks, Director of FDA's Center for Biologics Evaluation and Research, and Steven Solomon, Director of FDA's Center for Veterinary Medicine, say the authors' criticisms are inaccurate with respect to the United States
- FDA points to the December 2020 approval of the GalSafe pig, which has an intentional genomic alteration, as an indication of its functioning regulatory system

Nature Biotechnology: Clarifying US regulations on xenotransplantation

# The International Xenotransplantation Association (IXA) also criticizes the July 2021 commentary, for not noting IXA's published regulatory guidelines

- "IXA is concerned that readers of the Correspondence may be tempted to draw the incorrect conclusion that
  there are few if any efforts being made to provide common standards and guidelines for the regulation of
  clinical xenotransplantation."
- The piece goes on to chronicle international efforts, under the WHO, to develop harmonized approached to xenotransplantation regulation

Nature Biotechnology: International standards and guidelines for xenotransplantation

## The authors of the July 2021 commentary defend their original message

- The authors say the criticisms do not pertain to the intended scope of their piece
- They stress that their scope was narrow, and that they merely intended to stimulate discussion and point out that work remains to be done

Nature Biotechnology: Reply to 'Clarifying US regulations on xenotransplantation' and 'International standards and guidelines for xenotransplantation'

Nature Biotechnology: (Original Commentary) Regulatory and intellectual property conundrums surrounding xenotransplantation

### **SCIENCE**

### New haploid inducing mutation identified in corn

- PHOSPHOLIPASE D3 (ZmPLD3) mutants have >1% haploid induction
- Combining PLD3 mutations with mutations in other known haploid inducing genes resulted in synergistic increase to >4%

Nature Plants: Loss-of-function alleles of ZmPLD3 cause haploid induction in maize

## "Twin prime editing" combines two prime editing tools to allow large DNA insertions and inversions without double stranded breaks

- Prime editing involves nicking DNA with a site-specific nuclease that is attached to a repair template
- Complimentary prime editing tools allow complex DNA changes without the unintended recombination that can accompany double strand breaks
- The tool was demonstrated in human cells

Nature Biotechnology: Programmable deletion, replacement, integration and inversion of large DNA sequences with twin prime editing

## Corteva publishes environmental risk assessment of DvSSJ1 insecticidal double stranded RNA and IPDD072Aa insecticidal protein

This RNA and this protein are present in Corteva's DP23211 corn

GM Crops & Food: Environmental risk assessment of the DvSSJ1 dsRNA and the IPD072Aa protein to non-target organisms

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